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10/586,052	07/14/2006	Minami Matsui	P30310	2446

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EXAMINER	
WORLEY, CATHY KINGDON	
ART UNIT	PAPER NUMBER
1638	

NOTIFICATION DATE	DELIVERY MODE
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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Office Action Summary	Application No.	Applicant(s)	
	10/586,052	MATSUI ET AL.	
	Examiner	Art Unit	
	CATHY K. WORLEY	1638	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *01 April 2008*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-12* is/are pending in the application.

4a) Of the above claim(s) *2,3,10 and 12* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1, 4-9, and 11* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *14 July 2006* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *11/14/06; 4/16/07*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Restriction/Election

1. In response to the communication received on April 1, 2008, from Bruce H. Bernstein, the election without traverse of group I, claims 1, 4-9, and 11, is acknowledged. Claims 1-12 are pending in the instant application. Claims 2, 3, 10 and 12 are withdrawn because they are directed to non-elected inventions. Claims 1, 4-9, and 11 are examined in this Office Action. This restriction requirement is MADE FINAL.

Information Disclosure Statement

2. The information disclosure statement filed Nov. 14, 2006, fails to comply with 37 CFR 1.98(a)(2), which requires a legible copy of each cited foreign patent document; each non-patent literature publication or that portion which caused it to be listed; and all other information or that portion which caused it to be listed. Two of the foreign patent documents were not received, and the Examiner has lined through those items. The IDS has been placed in the application file, but the information referred to in the items lined through therein has not been considered.

Specification

3. The abstract of the disclosure is objected to because the clean copy of the abstract submitted on July 14, 2006, does not match the abstract from the WIPO document (WO 2005/068631). The new abstract should be submitted as a clearly labeled replacement abstract; or alternatively, the amendments to the abstract should be underlined for insertions and striked through for deletions. Correction is requested. See MPEP § 608.01(b).

4. The use of the trademark SILWET L-77 has been noted in this application. Trademarks should be written in all capital letters wherever they appear; or alternatively, they should be denoted with the registered trademark symbol, ®, and be accompanied by the generic terminology.

Although the use of trademarks is permissible in patent applications, the proprietary nature of the marks should be respected and every effort made to prevent their use in any manner which might adversely affect their validity as trademarks.

Claim Objections

5. Claim 1 is objected to because of the following informalities: it is missing an article in line 1 and the wording is awkward. The Applicant is advised to insert - -

an - - between "as" and "IRES". The Applicant is advised to replace "located downstream along the translation direction in the plant" with language that is less awkward; ie. - - located downstream thereof - - or - - operably linked thereto - - or - - ; wherein the DNA is located between a promoter and coding sequence - - .

Claims 7-9 are objected to because they utilize an improper article for a dependent claim. The Applicant is advised to replace "a polynucleotide" with - - the polynucleotide - - .

Claim 11 is objected to because it utilizes an improper article for a dependent claim. The Applicant is advised to replace "a vector" with - - the vector - - .

Appropriate correction is requested.

Claim Rejections - 35 USC § 101

35 U.S.C. 101 reads as follows:

> Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

6. Claims 1 and 4-6 are rejected because the claimed invention is directed to non-statutory subject matter.

The claims read on a molecule per se which is found in nature and thus, is unpatentable to Applicants. DNA that occurs in nature in a wild-type Arabidopsis plant comprises the polynucleotide of SEQ ID NO:1, therefore claim 1, as written, encompasses a naturally occurring molecule, and therefore does not constitute patentable subject matter. See *American Wood v. Fiber Disintegrating Co.*, 90 U.S.

566 (1974), *American Fruit Growers v. Brodgex Co.*, 283 U.S. 2 (1931), *Funk Brothers Seed Co. v. Kalo Inoculant Co.*, 33 U.S. 127 (1948), *Diamond v. Chakrabarty*, 206 USPQ 193 (1980).

The added limitations in claims 4 and 5 regarding repeats do not distinguish the claimed polynucleotide from a naturally occurring polynucleotide, because the DNA of (b) can be a single nucleotide after deletions and substitutions (ie. DNA (b) could be a "T") and because there can be any spacer sequence between the repeats; and therefore, it encompasses wild-type sequences. The added limitation in claim 6 does not distinguish the claimed polynucleotide from a naturally occurring polynucleotide because the chromosomal DNA of a wild-type Arabidopsis plant inherently comprises promoters and genes.

It is suggested that the recitation - - An isolated - - be inserted in place of "A" in claim 1 to overcome this rejection.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

7. Claims 1, 4-9, and 11 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. All depended claims are included in this rejection.

The recitation in claims 1 and 6 is indefinite because of the recitation "gene" which is confusing since the limitation "gene" encompasses the coding sequence and the associated promoter, terminator and enhancer encoding regions, as well as introns (see The Federal Register, Vol. 66, No. 4, Friday, January 5, 2001 at page 1108, left column, Endnote 13). In the instant case, Applicants do not appear to describe such "gene" associated nucleic acid sequences; they only utilize the coding sequences downstream of the internal ribosome entry site (IRES) of the instant invention. It is suggested that "gene" be amended to recite a polynucleotide or a nucleic acid or a coding sequence.

8. Claims 1, 4-9, and 11 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The claims are broadly drawn to a polynucleotide which functions as an IRES in a plant and comprises "a" DNA of SEQ ID NO:1 or a DNA derived from SEQ ID

NO:1 by the substitution, deletion, addition, and insertion of one or more bases; and to a vector and plant comprising said polynucleotide. The claims include constructs with repeats of the polynucleotide.

The Applicants describe the nucleic acid of SEQ ID NO:1 which is 12 nucleotides in length (see sequence listing). They describe a construct comprising 10 repeats of SEQ ID NO:1 with spacer sequences between the repeats (see paragraph 0060 on page 17), and they describe a construct comprising 10 repeats of SEQ ID NO:1 without spacer sequences (see first paragraph on page 21). The Applicants describe an IRES from ECMV that is known to function in mammal cells and tobacco (see last paragraph on page 18) and a construct comprising this ECMV IRES (see second paragraph on page 21). They describe transgenic Arabidopsis plants transformed with these constructs (see page 19); and they describe the effect on expression from using 10 repeats without spacers as "far increased" (see paragraph bridging pages 21-22) and the effect on expression from using 10 repeats with spacers as “slightly increased” (see second paragraph on page 22). They describe the effect on expression from using the ECMV IRES as not increased (see third paragraph on page 22).

The Applicants do not describe any DNAs “derived from” SEQ ID NO:1 that function as an IRES. The Applicants do not describe SEQ ID NO:1 as having IRES activity in any plant other than Arabidopsis.

The Federal Circuit has recently clarified the application of the written description requirement to inventions in the field of biotechnology. The court stated that, "A description of a genus of cDNAs may be achieved by means of a recitation of a representative number of cDNAs, defined by nucleotide sequence, falling within the scope of the genus or of a recitation of structural features common to members of the genus, which features constitute a substantial portion of the genus." See *University of California v. Eli Lilly and Co.*, 119 F. 3d 1559; 43 USPQ2d 1398, 1406 (Fed. Cir. 1997).

The Applicants fail to describe a representative number of DNAs "derived from" SEQ ID NO:1 that have IRES activity. The Applicants only describe a construct with 10 repeats of SEQ ID NO:1. Furthermore, the Applicants fail to describe structural features common to members of the claimed genus of SEQ ID NO:1 derivatives. Hence, Applicants fail to meet either prong of the two-prong test set forth by *Eli Lilly*. Furthermore, given the lack of description of the necessary elements essential for IRES function, it remains unclear what features identify SEQ ID NO:1 derivatives capable of such activity. Since the genus of DNAs derived from SEQ ID NO:1 has not been described by specific structural features, the specification fails to provide an adequate written description to support the breadth of the claims.

DNAs that are derived from SEQ ID NO:1 by substitution, deletion, addition, and insertion encompass an infinite number of molecules, many of which would not

have IRES activity in a plant, and most of which were not in the possession of the Applicant at the time of filing. The Applicants have only reduced to practice in an experiment that demonstrates IRES activity, a polynucleotide comprising 10 repeats of SEQ ID NO:1 which is shown to be active only in Arabidopsis plants. Accordingly, the specification fails to provide an adequate written description to support the genus of DNAs derived from SEQ ID NO:1 that have IRES function as set forth in the claims. (See Written Description guidelines published in the Federal Register/Vol. 66, No. 4/Friday, January 5, 2001/Notices: p. 1099-1111).

9. Claims 1, 4-9, and 11 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a polynucleotide comprising 10 repeats of SEQ ID NO:1 that functions as an IRES in Arabidopsis, and a vector comprising said polynucleotide and a transformed Arabidopsis plant comprising said polynucleotide, does not reasonably provide enablement for a polynucleotide comprising "a" DNA of SEQ ID NO:1 or a DNA "derived from" SEQ ID NO:1, or for IRES activity in any plant other than Arabidopsis. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

The claimed invention is not supported by an enabling disclosure taking into account the *Wands* factors. *In re Wands*, 858/F.2d 731, 8 USPQ2d 1400 (Fed. Cir.

1988). *In re Wands* lists a number of factors for determining whether or not undue experimentation would be required by one skilled in the art to make and/or use the invention. These factors are: the quantity of experimentation necessary, the amount of direction or guidance presented, the presence or absence of working examples of the invention, the nature of the invention, the state of the prior art, the relative skill of those in the art, the predictability or unpredictability of the art, and the breadth of the claim.

The claims are broadly drawn to a polynucleotide which functions as an IRES in a plant and comprises "a" DNA of SEQ ID NO:1 or a DNA derived from SEQ ID NO:1 by the substitution, deletion, addition, and insertion of one or more bases; and to a vector and plant comprising said polynucleotide. The claims include constructs with repeats of the polynucleotide. The use of the article "a" in front of "DNA of the nucleotide sequence represented by SEQ ID NO:1" renders this claim inclusive of fragments of SEQ ID NO:1 as small as dinucleotides.

The Applicants teach the nucleic acid of SEQ ID NO:1 which is 12 nucleotides in length (see sequence listing). They teach a construct comprising 10 repeats of SEQ ID NO:1 with spacer sequences between the repeats (see paragraph 0060 on page 17), and they teach a construct comprising 10 repeats of SEQ ID NO:1 without spacer sequences (see first paragraph on page 21). The Applicants teach an IRES from ECMV that is known to function in mammal cells and tobacco (see last paragraph on page 18) and a construct comprising this ECMV IRES (see second

paragraph on page 21). They teach transgenic Arabidopsis plants transformed with these constructs (see page 19); and they teach that the effect on expression from using 10 repeats without spacers was "far increased" (see paragraph bridging pages 21-22) and the effect on expression from using 10 repeats with spacers was "slightly increased" (see second paragraph on page 22). They teach that the effect on expression from using the ECMV IRES was not increased (see third paragraph on page 22).

The Applicants do not teach any DNAs "derived from" SEQ ID NO:1 that function as an IRES, nor do they teach any fragments of SEQ ID NO:1 that function as an IRES. The Applicants do not teach that SEQ ID NO:1 has IRES activity in any plant other than Arabidopsis, and they do not teach that it has IRES activity when there are less than 10 repeats of SEQ ID NO:1 present.

For example, the state-of-the-art is such that one of skill in the art cannot predict which species of plants a nucleic acid will function as an IRES in; see Applicant's own data demonstrating that the ECMV IRES that functions and mammalian and tobacco cells did not function in Arabidopsis (see third paragraph on page 22; and see Urwin et al (2000) The Plant Journal; Vol. 24, pp. 583-589). As discussed above, the recitation of a DNA "derived from" SEQ ID NO:1 includes an infinite number of molecules, and the instant specification has not provided any guidance about what nucleotides can be substituted, deleted, or added and still retain IRES activity. In addition, the recitation of "a" DNA of SEQ ID NO:1 is

inclusive of fragments as small as dinucleotides, and the instant specification has not provided any guidance about which nucleotides can be deleted and how small of a fragment would be effective as an IRES.

Given the lack of guidance in the instant specification, undue trial and error experimentation would be required for one of skill in the art to make an endless number of fragments of SEQ ID NO:1 or DNAs "derived from" SEQ ID NO:1, and test each one for IRES activity. One of skill in the art would be left to transform multitudes of different plant species to determine in which plants (if any other than Arabidopsis) the nucleic acid of SEQ ID NO:1 can function as an IRES.

Therefore, given the breadth of the claims; the lack of guidance and working examples; the unpredictability in the art; and the state-of-the-art as discussed above, undue experimentation would be required to make and use the claimed invention, and therefore, the invention is not enabled throughout the broad scope of the claims.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

10. Claims 1, 4-6, 8, and 9 are rejected under 35 U.S.C. 102(b) as being anticipated by Alonso et al (GenBank Accession BH789726 (2002), pp. 1-2).

The claims are drawn to a polynucleotide which functions as an IRES in a plant and comprises "a" DNA of SEQ ID NO:1 or a DNA "derived from" SEQ ID NO:1 by the substitution, deletion, addition, and insertion of one or more bases; and to a vector and plant comprising said polynucleotide. The claims include constructs with repeats of the polynucleotide. The use of the article "a" in front of "DNA of the nucleotide sequence represented by SEQ ID NO:1" renders this claim inclusive of fragments of SEQ ID NO:1 as small as dinucleotides and the recitation of "derived from" renders this claim inclusive of any single nucleotide.

Alonso et al teach a nucleic acid that comprises the complete nucleotide sequence of SEQ ID NO:1 (see alignment and see reference provided with restriction requirement). This nucleic acid inherently has the property of IRES activity in Arabidopsis plants. Claim 4 recites repeats of DNA (a) or (b); and the nucleic acid taught by Alonso et al comprises one polynucleotide of SEQ ID NO:1, but in addition, it comprises multiple fragments of SEQ ID NO:1, and multiple "derivatives" of SEQ ID NO:1; for example there are ten "T"s and a "T" is a

derivative of SEQ ID NO:1. The sequence taught by Alonso et al comes from a TDNA insertion line (see "Definition"); and these insertion lines comprises the NPTII gene as a selectable marker that comprises a promoter that functions in plants. These TDNA insertion lines are transgenic plants that have a polynucleotide incorporated in the genome, including the nucleic acid taught by Alonso et al which comprises a sequence with 100% identity to SEQ ID NO: 1.

11. Claims 1, 4-9, and 11 are rejected under 35 U.S.C. 102(a) and 35 USC 102(e) as being anticipated by La Rosa et al (US 2004/0031072 A1; published on Feb. 12, 2005, filed as Application No. 10/424,599 on April 28, 2003, with priority to Application No. 09/304,517 which was filed on May 6, 1999). Applicant cannot rely upon the foreign priority papers to overcome this rejection because a translation of said papers has not been made of record in accordance with 37 CFR 1.55. See MPEP § 201.15. The rejection under 35 USC 102(a) will be withdrawn if the Applicant provides a translation of the foreign priority document JP 2004-008025 and if the foreign priority document provides adequate support for the claimed invention. The rejection under 35 USC 102(e) cannot be overcome by providing a translation of the foreign priority document.

The claims are drawn to a polynucleotide which functions as an IRES in a plant and comprises SEQ ID NO:1; and to a vector and plant comprising said polynucleotide. The claims include constructs with repeats of the polynucleotide.

The use of the article "a" in front of "DNA of the nucleotide sequence represented by SEQ ID NO:1" renders this claim inclusive of fragments of SEQ ID NO:1 as small as dinucleotides and the recitation of "derived from" renders this claim inclusive of any single nucleotide.

La Rosa et al teach a nucleic acid comprising a polynucleotide with 100% identity to the instant SEQ ID NO:1 (see alignment). They refer to this nucleic acid as SEQ ID NO:122,992. This nucleic acid inherently has the property of IRES activity in Arabidopsis plants. Claim 4 recites repeats of DNA (a) or (b); and the nucleic acid taught by La Rosa et al comprises one polynucleotide of SEQ ID NO:1, but in addition, it comprises multiple fragments of SEQ ID NO:1, and multiple "derivatives" of SEQ ID NO:1; for example there are ten "T"s and a "T" is a derivative of SEQ ID NO:1. They claim a recombinant DNA construct comprising this polynucleotide (see claim 1); and they teach a method of producing a plant having an improved property, by transforming a plant with a construct comprising the polynucleotide and a promoter (see claim 3). They teach vectors comprising this polynucleotide (see page 7, paragraph 0068), and they teach transformation of plants with these vectors (see page 8).

12. Claims 1, 4-9, and 11 are rejected under 35 U.S.C. 102(b) as being anticipated by Akbergenov et al (Nucleic Acids Research (2004) Vol. 32, pp. 239-247; published online Jan. 12, 2004). Applicant cannot rely upon the foreign priority papers to

overcome this rejection because a translation of said papers has not been made of record in accordance with 37 CFR 1.55. See MPEP § 201.15. The rejection under 35 USC 102(b) will be withdrawn and replaced with a rejection under 35 USC 102(a) if the Applicant provides a translation of the foreign priority document JP 2004-008025 and if the foreign priority document provides adequate support for the claimed invention.

The claims are drawn to a polynucleotide which functions as an IRES in a plant and comprises SEQ ID NO:1; and to a vector and plant comprising said polynucleotide. The claims include constructs with repeats of the polynucleotide. The use of the article "a" in front of "DNA of the nucleotide sequence represented by SEQ ID NO:1" renders this claim inclusive of fragments of SEQ ID NO:1 as small as dinucleotides and the recitation of "derived from" renders this claim inclusive of any single nucleotide.

La Rosa et al teach a nucleic acid comprising a polynucleotide with 100% identity to the instant SEQ ID NO:1 (see alignment). They refer to this nucleic acid as SEQ ID NO:122,992. This nucleic acid inherently has the property of IRES activity in Arabidopsis plants. Claim 4 recites repeats of DNA (a) or (b); and the nucleic acid taught by La Rosa et al comprises one polynucleotide of SEQ ID NO:1, but in addition, it comprises multiple fragments of SEQ ID NO:1, and multiple "derivatives" of SEQ ID NO:1; for example there are ten "T"s and a "T" is a derivative of SEQ ID NO:1. They claim a recombinant DNA construct comprising

this polynucleotide (see claim 1); and they teach a method of producing a plant having an improved property, by transforming a plant with a construct comprising the polynucleotide and a promoter (see claim 3). They teach vectors comprising this polynucleotide (see page 7, paragraph 0068), and they teach transformation of plants with these vectors (see page 8).

13. No claim is allowed.

14. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Cathy K. Worley whose telephone number is (571) 272-8784. The examiner is on a variable schedule but can normally be reached on M-F 10:00 - 4:00 with additional variable hours before 10:00 and after 4:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anne Marie Grunberg, can be reached on (571) 272-0975. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/Cathy K. Worley/
Patent Examiner, Art Unit 1638